IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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ACTELION PHARMACEUTICALS LTD., et al., Plaintiffs	:	CIVIL ACTION NO. 12-5743
v.	:	Camden, New Jersey
	:	March 12, 2013
APOTEX INC., et al., Defendants	:	10:06 o'clock a.m.

HEARING ON MOTION TO STAY
BEFORE THE HONORABLE ANN MARIE DONIO
UNITED STATES DISTRICT COURT JUDGE

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(The following occurred in open court at 10:06 o'clock a.m.:)

THE COURT: We are here on the record for a hearing on a motion to stay in Case Number 12-5743. This hearing and argument is being electronically recorded. I would ask that each time you speak you identify yourself for the record.

We'll begin by having the attorneys place their appearances on the record, beginning with plaintiffs' counsel.

MR. GORDON: Good morning, George Gordon from Dechert LLP for Actelion Pharmaceuticals Limited and Actelion Clinical Research.

THE COURT: All right, thank you.

MS. YEARY: Michelle Yeary, also from Dechert, for Actelion Pharmaceuticals and Actelion Limited.

THE COURT: Anyone else from plaintiff?

MS. BUDZINSKI: Carolyn Budzinski for Actelion.

MR. CAROLINE: And David Caroline from Dechert for Actelion.

THE COURT: All right, thank you.

Okay, for defendants?

MR. GOELMAN: Good morning, your Honor, Aitan Goelman from Zuckerman Spaeder for Apotex. With me at counsel table is Paul Hynes from Zuckerman Spaeder and with us in court is local counsel, Michael Shapiro of Bazelon Less

& Feldman, also for Apotex.

THE COURT: Thank you.

MS. REEVES: Amanda Reeves, Latham & Watkins, on behalf of Actavis Elizabeth. With me also is our local counsel, Jason Lattimore of the Lattimore Law Firm.

THE COURT: All right, thank you.

MS. EUN: Good morning, your Honor, Eunnice Eun from Kirkland & Ellis for Roxane, and with me today is our local counsel, Charles Falletta.

THE COURT: All right. Welcome, everyone.

All right. This is the plaintiffs' motion to stay discovery pending resolution of a dispositive motion presently before the District Court, and that's a motion for judgment on the pleadings. I have reviewed the submissions and I'm ready to hear any additional argument, and we'll begin with plaintiffs' counsel.

MR. GORDON: Thank you, your Honor.

THE COURT: Just state your name, please, before you speak.

MR. GORDON: George Gordon on behalf of the plaintiffs.

Your Honor, Actelion has asked to stay discovery for a fairly simple and straightforward reason, and that is that the underlying dispositive motion in the case really asks the Court to resolve a fundamental threshold question, and that

is whether Actelion has an obligation under the circumstances alleged by the counterclaim plaintiffs to deal with those plaintiffs. The Court's answer to that question we believe should end this case; at the very least, it will shape the way the case will move forward, but we believe that the motion will actually obviate the need for any discovery.

And I think the cases cited in both sides' briefs make clear one thing and that is that such a stay is well within the discretion of the Court. We are not arguing that there is some per se right to a stay based on a dispositive motion, we understand that the character of the motion may bear on the Court's exercise of discretion. And if you look at the cases cited in the opposition to our motion by the counterclaim plaintiffs, I think, you know, fundamentally they stand for the principle that courts do sometimes exercise the discretion not to stay discovery based on circumstances that are not present in this case.

THE COURT: Well, let's speak a little bit about those circumstances.

MR. GORDON: Sure.

THE COURT: You filed the complaint for declaratory action?

MR. GORDON: Correct.

THE COURT: How soon from the filing of the complaint did you move for the stay?

MR. GORDON: We moved for the stay shortly after receiving -- I guess it was in January, your Honor, when we -- we filed the complaint in September and moved for the stay in January after receiving the counterclaims.

THE COURT: All right. And there was -- I mean, this issue was discussed at the initial -- what was the initial conference, right?

MR. GORDON: Yes, your Honor.

THE COURT: So there was no scheduling order in place because we've had this pending motion?

MR. GORDON: Correct.

THE COURT: Okay. There's argument by defense counsel concerning prejudice to the defendant; can you address that argument?

MR. GORDON: Sure. I think the argument -- and our response is twofold on the prejudice issue. First, it's -- you know, prejudice, the issue of prejudice is one of the things that used to be weighed in the exercise of discretion, it's one of the factors. I think the first issue to keep in mind is that the return date on the underlying dispositive motion is right around the corner, it's April 1. I don't presume to know on what schedule may want to hear argument, whether the Court is going to want to hear argument or decide the dispositive motion, but I would not expect this is a stay of potentially indefinite duration, as was the case in many

of the stays that were at issue in the cases that the defendants cite. You know, this is a far cry from a case, for example, your Honor, where there is a stay pending in an underlying criminal investigation.

THE COURT: Well, we -- you could say that's a different type of circumstance.

MR. GORDON: So I think it bears on prejudice, your Honor, because it bears on the potential duration of the stay.

THE COURT: As I would agree in a stay pending a reexamination.

MR. GORDON: Correct.

THE COURT: Where we have a limited time period.

MR. GORDON: Correct.

THE COURT: And I guess that's really going to be up to the District Judge.

MR. GORDON: It's a limited time period. I think also when you weigh the prejudice as against the time that had elapsed before these issues were brought to the Court's attention, which were brought to the Court's attention by Actelion --

THE COURT: Now, can you flesh that argument out?

MR. GORDON: Sure. Apotex I believe first requested samples of Tracleer in January of 2011 and those -- those requests were not responded to by Actelion, that's accurate.

But we heard nothing from Apotex again on those requests for about 17, 18 months until June of 2012 when counsel for Apotex reached out to Actelion once again. We engaged in discussions at that point to see if the issue could be resolved and we were unable to resolve it, which led to Actelion, because Actelion wanted its rights to be declared by the Court here, to file the action for declaratory judgment. So there that's, you know, 18 months during which nothing was done with respect to the request for samples. So, from Actelion's perspective, you know, the cry of urgency and prejudice now rings a bit hollow, particularly in light of the fact that we're dealing with the stay of temporary duration.

And I think, you know, weighed against that prejudice is the prejudice to Actelion of having to engage in discovery in a case that we believe, for the reasons expressed in our dispositive motion, is not meritorious and should not have been -- we should not have to be here litigating these issues.

THE COURT: All right, let's talk about that a minute. Because the factors include prejudice, although sometimes the Court looks at prejudice to one side and not the other, I'm going to examine prejudice to both sides when I examine the factors. So the defendants take exception to any prejudice to the plaintiff in the idea that there was a

phase discovery outlined and that why stay discovery now if we could just begin with written discovery, wouldn't that lessen the impact of any, quote, "prejudice," quote, to the plaintiffs?

MR. GORDON: Well, the phase discovery, as I understand it, as proposed by the defendants, was not merely kind of an exchange of written discovery, what it involved was document production of certain categories of hard copy documents, as well as, you know, other forms of interrogatories and written discovery. What would really be -- as I understand the proposal, what might have been put off were depositions and electronic discovery.

Now, it raises a number of questions in terms of, you know, there's a lot packed into even hard-copy document discovery. I mean, hard-copy document discovery requires a search of files. It's not clear from the proposal whether or not the first phase would include non-e-mail electronic discovery. So if I have a document that's on a server, it's not an e-mail but it's a memo, is that hard-copy discovery or not? Would we have to search twice effectively? I mean, you know, phase discovery sounds on its face like it can save expenses, in some instances it can actually be more burdensome because it requires duplicative searching. So we would have to search the files of the particular custodians in Phase 1 for certain hard-copy documents and then perhaps

again in Phase 2 for e-mails and electronic documents. So even a phase discovery process, your Honor, in the first phase as I understand being proposed by the defendants, could be quite costly and expensive. And it's not just the financial cost, it's the distraction of management time and, you know, other non-financial burden that goes along with engaging in discovery in complex litigation like this one.

THE COURT: And that is the prejudice to your client?

MR. GORDON: Yes, your Honor.

THE COURT: Okay. Anything further?

MR. GORDON: I mean, I guess in -- you know, we do not believe, your Honor, that you need to decide effectively, as the defendants suggest, the underlying dispositive motion. We believe that the character of the motion is one that is dispositive, comprehensive. We're not complaining -- if you look at some of the cases that are cited in the defendants' brief, the Coca-Cola Bottling Company of Lehigh is one for example where the court looked at the motion to dismiss and said, you know, you're really moving to dismiss on technical pleading defects; this can be fixed, so it may not be dispositive. This motion is dispositive and we would suggest that the Court be guided by the approach the Court took in the Wiessman v. Meta (ph.) case where the Court did take a look at the motion to dismiss in that case, not on the

merits, but to confirm that it would indeed be dispositive if decided in the defendant's favor and decided on that basis, along with the definite duration and what the Court believed would be a relatively short duration of the stay, and granted the stay.

And here, I think just as context, it's important to understand that the dispositive motion does raise what is the request for fairly extraordinary relief from the counterclaim defendants here in forcing Actelion to actually sell samples to them against their will. I mean, that -- what hangs in the balance is a fairly sacrosanct commercial freedom to decide with whom one does business and under what circumstances that right can be circumscribed. And just to counter one impression I think created by the briefings that is not accurate, this is not -- we're not talking about chewing gum here, your Honor, this is not a simple sale of a product. What goes along with the sale of this product, the defendants themselves acknowledge that these are products, Tracleer and Zyveska (ph.), that have serious safety concerns, which is why the FDA required restrictive-distribution plans. Their response to that is, well, we've told Actelion we can handle it, don't worry about it. Actelion is not required and frankly can't just rely on that. So, in addition to a sale, we're talking about efforts that would include confirming the defendants' ability to rely

on -- or the ability to take care of the safety issues and ongoing monitoring of that ability during the testing, which does involve the administration of these products to patients.

So I just want to put that in context, put the request for stay in a context of the nature of the issues that are being dealt with in the dispositive motion.

THE COURT: Okay. So you've addressed the factors of prejudice and the status of the dispositive motion. Are there any other factors you think the Court should be considering in determining whether a stay is appropriate?

MR. GORDON: No, I think, your Honor, it really hangs on the nature of the dispositive motion and the prejudice to Actelion in allowing discovery to move forward, as well as really the absence of prejudice to the defendants of a stay of the type that we're requesting.

THE COURT: And you would agree that it's your burden under Rule 26(c) to demonstrate good cause for the stay?

MR. GORDON: Yes, your Honor. I don't have an issue with that, we believe that we've demonstrated that.

THE COURT: Anything further for now?

MR. GORDON: Nothing, your Honor.

THE COURT: All right, thank you.

From defendants?

MR. GOELMAN: Thank you, your Honor, Aitan Goelman for Apotex.

I want to begin with something that Counsel for Actelion said. He said that the parties recognize that the Court has discretion here to go either way on the motion for stay and certainly we wouldn't argue that there's no discretion on the part of a judge to grant motions for stay of discovery; that discretion, however, is cabined by what the legal standard is. And in addition to the fact that Actelion has to -- has the burden for showing good cause, the case law in this district is pretty clear that motions for stay of discovery are disfavored and that there are two prongs that the opposing party has to meet in terms of their burden. They have to show clearly and unmistakably that they can win their dispositive motion, there's only one way to go.

THE COURT: What's the case that supports that position that they have to demonstrate clearly and unmistakably that the plaintiff will prevail on the motion?

MR. GOELMAN: Castro v. Sanofi Pasteur, it's District of New Jersey, Magistrate Judge Hammer, 2012.

THE COURT: All right. What does the Third Circuit have to say about that though? What does the Mann case say? Doesn't that give me as the Magistrate Judge discretion in looking at the issue of stay and didn't the Third Circuit affirm a stay of discovery?

MR. GOELMAN: I think that the Third Circuit did affirm a stay of discovery there, I think that the facts of that case are distinguishable. And certainly, you know, as I said in the beginning of the argument, we're not arguing that the Court does not have discretion. I think that the standard in this district though is that it's a pretty heavy burden for the party moving for a stay of discovery to meet.

THE COURT: Well, let me couch my question in this way. There are a couple cases from Magistrate Judges that have denied stays and then there are cases that have granted stays in other districts, and we have the Third Circuit saying, yes, a stay may be appropriate. So, as I view it, I have discretion and I have to look at the various factors. And the plaintiffs' counsel's argument is it's very fact-specific; look at the nature of the dispositive motion, look at the time table, look at the prejudice. Isn't that accurate, isn't that what I'm supposed to be examining?

MR. GOELMAN: Yes.

THE COURT: Okay. So why don't you, if you can, address those specific issues on prejudice to defendant if I grant a stay.

MR. GOELMAN: Okay.

THE COURT: Whether you accept there's any prejudice to the plaintiff or not and the nature of the dispositive motion. Because I'm not sure the standard is I have to find

whether the dispositive motion is clearly and unmistakably correct, because wouldn't that in effect require me to decide the dispositive motion?

MR. GOELMAN: It requires you to evaluate the dispositive motion and try to make a judgment about how likely it is to be granted. I think that that is one part of the test that courts faced with a motion for a stay of discovery are supposed to perform.

THE COURT: Okay.

MR. GOELMAN: But in terms of prejudice, let me just address that first, because the Court said during the colloquy with Counsel for Actelion that, you know, the Court is going to consider prejudice to both parties here. We agree you should consider prejudice to both parties, but we think that you also should consider prejudice to others, to people who aren't parties here; to the people who are paying super-competitive prices for Actelion's drugs for every day, to the third-party insurers, to the United States Government, to the people who are going to pay during the pendency of this case, you know, hundreds of millions of dollars additionally because of Actelion's maintenance of a monopoly in these two different drugs. And we would -- I don't know if the Court has had a chance, you said that you've read the submissions of the parties, I don't know if you've had a chance to read the submissions by the two amici that were

filed --

THE COURT: Well, they were filed last night?

MR. GOELMAN: They were filed last night.

THE COURT: No, I have not had an opportunity to examine that.

MR. GOELMAN: One of the amici is the FTC and the FTC -- you know, they are typically very guarded and cautious and I don't want to say mealy-mouthed, because that's pejorative, but they're very -- they're not partisan -- that they take a very strong position in this case that the facts, if proven, as alleged by the counterclaim plaintiffs and defendants here do make out Section 2 and Section 1 claims under the Sherman Act. So I think that that militates very strongly in favor of skepticism that Actelion's dispositive motion is going to be granted.

And the FTC's amicus also talks about how fact-intensive Section 2 evaluation is. This is not, as Actelion would have the Court believe, only a legal question. Clearly there are legal questions that Judge Hillman will have to decide in considering the dispositive motion, but there's also factual questions in the case and every month of delay that Actelion buys itself here is another month that it can maintain its monopoly on the far side of the expiration of the patent.

And I want to respond in particular to one thing

that Counsel for Actelion said, because I really think it shows, and I hesitate to use a Yiddish word in Federal Court, but chutzpa. The idea that Apotex because it's asked for these samples in January of 2011 and then didn't institute a law suit until it was sued by Actelion a year and a half later doesn't really care about speed is just not true. And it's, first of all, factually inaccurate. After Apotex sent a letter to Actelion in January, 2011 and got no response from Actelion, it sends another letter in April, 2011 and again got no response from Actelion. Then it tried to figure out a way to bring its ANDA using a Canadian version of Tracleer. And eventually the FDA said, no, you have to use the American RLD.

So the idea that Actelion, which has bought itself an extra 18 months by refusing to respond even to these letters demanding Tracleer until Apotex got outside counsel involved, can then later sue and turn and point to the delay as evidence that Apotex doesn't really care about a delay is frankly offensive and inaccurate.

THE COURT: Can you just while we're on the topic of the time line flesh out for me the argument about, if you were -- I just want to understand how the process works -- if the defendant is able to get a sample, what's the time line generally before you would be in a position to file an ANDA?

MR. GOELMAN: Well, you have to perform these

bioequivalence studies with the RLD and --

THE COURT: Can you say that and spell that word again for the record, because I'm not sure I heard the bio --

MR. GOELMAN: Bioequivalence --

THE COURT: Bioequivalence, okay.

MR. GOELMAN: -- b-i-o equivalence. You have to take the drug to the RLD and you have to show certain things in a lab, like the rate of absorption, and that your generic alternative is the same, it's bioequivalent to the RLD. And after you do that, only after you do that can you file the ANDA, the Abbreviated New Drug Application. And then from the time that you file the ANDA to the time that the ANDA is actually granted, assuming it would be granted, can be, you know, at least two years, maybe 30 months.

So right now they have a patent on Tracleer, just to focus on that one drug, and that patent I think expires in November, 2015. Even assuming the validity of that patent -- and the Court should recall that in patent litigation over brand name drugs, often the patent is held to be invalid or not infringed by the generic competitor -- but even assuming that the patent is valid, that will run in November, 2015. So every month of delay that they buy now by preventing potential generic competitors from getting access to drugs that they need for bioequivalence is another month later that the process is pushed down the road. Because the FDA is

going to take the time that the FDA needs to evaluate the ANDA, it doesn't happen overnight.

So when we say that, you know, we are prejudiced by a stay of discovery, we mean that, you know, the process -- once the dispositive motion is decided and presumably denied, these discovery steps are going to have to take place in any case and we wanted to get started on that now. And the suggestion of phase discovery is a compromise proposal that we came up with because Actelion resisted any discovery at all, wanted a stay. If as Counsel appeared to argue that there are certain ways that phase discovery is actually more burdensome or more expensive than doing everything in one fell swoop, we're happy to do non-phase discovery as well. We came up with the phase proposal because we thought that delaying e-discovery, which some courts have cited as being expensive, and by delaying depositions, which we all know are expensive, that we would allow the first phase to take place without too much burden on the parties. And Actelion, for them to -- you know, they have this monopoly on a drug that makes them a billion dollars a year and for them to turn around, sue us and then ask for a stay of discovery because they don't want to spend the money to answer some interrogatories and provide some documents I think rings a little bit disingenuous when they claim that they want the case to proceed expeditiously.

THE COURT: What is the compromise provision? I know that at first -- your first position would be open discovery of all discovery, but as a compromise you've agreed or suggested in the papers to phase discovery. Can you describe exactly what you had in mind in that regard?

MR. GOELMAN: Sure, your Honor. Phase one would be written discovery, so your interrogatories and provision of core documents. And, you know, that obviously begs the question of what those core documents are. We believed that Actelion has already made a production to the FTC of relevant documents. So clearly, if that's true, they could just, you know, burn a copy onto a CD and provide it to us without incurring any additional costs really. But we would work out categories of what we consider to be core documents, including communications with distributors, communications with the FDA in preparation for the REMs, how the REMs -- you know, these are the restrictions on the use of particular brand drugs, how they were arrived at, things that probably have already been segregated into files at Actelion just because of the regular course of business.

And, you know, if there are requests, specific requests made that Actelion contends are overly burdensome, and we meet and confer and we can't work it out, at that point they always have the option to come to the Court for protection as they would in the normal course of the case

where they think that, you know, the equities weigh on their side that they shouldn't have to respond to a particular discovery request, as opposed to just a blanket prohibition on conducting any discovery at this point.

THE COURT: Okay. What about the plaintiffs' argument about prejudice to them, to it --

MR. GOELMAN: Prejudice to the plaintiffs?

THE COURT: The plaintiffs, two plaintiffs, prejudice to the plaintiffs.

MR. GOELMAN: About responding to discovery? Well, you know, if we -- first of all, I think that for them -- they filed suit, okay? So some -- in many of the cases where you're dealing with discovery stays that are granted, they're by -- brought by defendants who, you know, were dragged into court and they don't want to spend a whole lot of money defending a case when they think they're going to win on a dispositive motion. Here, they sued us. So I think that that weighs on the equities. And I do not believe that, especially if we follow this compromise proposal, phase discovery, that the burden is going to be undue. Certainly Actelion has made no showing, as is their burden, that complying with this discovery plan would create undue burdens.

THE COURT: And in addition to the prejudice -- you articulated the prejudice to the defendants and you've

indicated you assert prejudice to third parties for the inability to process and move forward with an ANDA and then creation of a generic drug?

MR. GOELMAN: Correct.

THE COURT: And you've articulated what you ascribe as lack of prejudice to the plaintiffs?

MR. GOELMAN: Correct.

THE COURT: Can you continue with your argument, because I think I interrupted you, on the standard of what I am to be examining with respect to the dispositive motion.

MR. GOELMAN: Okay. Well, I think that the Court should take a look at the dispositive motion and see if there is -- you know, the standard I believe in this district is that, you know, unmistakable, that there could be only one outcome and that is success for the dispositive motion, and that if the Court looks at the dispositive motion and finds that, you know, indeed there could be more than one outcome, that that in itself is a deal breaker for their motion for stay of discovery. And as a matter of fact in this case, I think that if a reader, a neutral, fair reader of the briefs on the dispositive motion would conclude that, to the extent that there is only one unmistakable outcome of this motion, it is that Actelion would lose, that their dispositive motion would be denied. And, again, I think the FTC amicus is telling in this regard, because they don't care about any of

us, they don't have a dog in the fight in terms of wanting one or more of the generic defendants here to make money, they are learned counsel on the antitrust laws and their concern is protecting the consumer from predatory, monopolistic behavior. And according to the FTC -- they're, you know, much more of an honest broker than either of the parties before this Court -- they don't believe that Actelion's motion should be granted or will be granted.

THE COURT: Do you agree with plaintiffs' Counsel that if the motion were to be granted this case would be over?

MR. GOELMAN: Yes.

THE COURT: Okay, let me see if I have any more questions.

(Pause.)

THE COURT: Okay, thank you. Is there anything further?

MR. GOELMAN: Just one thing. In terms of, you know, the hypothetical that Counsel for Actelion proposes is, one is they win the dispositive motion and the other one is that the dispositive motion is decided by the Court in a way that somehow narrows discovery, so that we would benefit from the guidance of that decision before starting discovery, our core discovery request, the phase one materials, they would be relevant in any case. As long as we survive the

dispositive motion, those are materials that are going to be, you know, centrally relevant to the litigation. So it's not like we need to wait for the decision by Judge Hillman in order to proceed with those targeted, focused, narrow discovery requests.

THE COURT: All right, thank you.

MR. GOELMAN: Thank you.

THE COURT: Any reply?

MR. GORDON: Just briefly, your Honor --

THE COURT: Sure.

MR. GORDON: -- if I may?

THE COURT: Oh, I'm sorry, did other defense counsel want to argue?

COUNSEL: We can talk while he argues and then if he has anything additional to say on that point, we're fine with that.

THE COURT: Okay.

MR. GORDON: George Gordon for the plaintiffs, your Honor. I just want to respond to a few points that Counsel made.

I mean, first of all, there's rhetoric in the brief and there's rhetoric in the argument about parties that are out there paying supposedly super-competitive prices for Actelion's products, I just want to make sure that the context and record is clear. Even if Actelion had provided

samples back in January or April of 2011, this is a patented product. Okay? There are a number of hurdles. It is likely and I would say, you know, virtually certain, there would not be an alternative product on the market today.

THE COURT: Well, let's just play that out. Let's assume right now there's a sample that's provided, maybe you lose the motion and the defendants are able to develop the testing that they need to do, they file their ANDA, then you would file suit and we'd have the stay, is that --

MR. GORDON: We would have an automatic -- correct, we would have a stay.

THE COURT: And then the patent will expire?

MR. GORDON: Correct.

THE COURT: Okay.

MR. GORDON: Yeah, that would have happened back -- I just want to point out that there's no one -- today we are not at a point in time where there would have been some alternative on the market, because even if that had started back in January of 2011 and they had been able to develop a bioequivalent product and they had filed an ANDA, we would be within the duration of the 30-month stay today.

THE COURT: Right. So isn't the 30-month stay regardless going to dovetail with the expiration of the patent? If there's a 30-month stay. I think we've only got the time line of one of the patents at issue.

MR. GORDON: Correct, on Tracleer. On Zyveska, the patents expire, the last-to-expire patent is in July of this year I believe.

THE COURT: Okay.

MR. GORDON: And Tracleer is November of 2015.

I also do want to respond -- I mean, you asked if the FTC filed an amicus brief, I don't believe that should bear at all on the Court's decision on the motion to stay. The FTC, I don't want to suggest they're not grounded as was observed by defense Counsel, but I will say they are very active in this area. They have filed amicus briefs with increasing frequency on behalf of generics in a variety of cases in the district court. So the fact that they -- just the mere fact that they have filed an amicus brief is not in any way a surprising event. And I will also say we have not -- let me make it clear, there was some suggestion we produced documents to the FTC, we have not produced any documents to the FTC.

THE COURT: In the present motion before the District Court that was filed last night was leave to file the brief.

MR. GORDON: And there was a brief attached to it as well, your Honor, a proposed --

THE COURT: And will you be opposing the --

MR. GORDON: We will not be opposing that, your

Honor.

THE COURT: And you'll send a letter to the District Judge on that?

MR. GORDON: Yes, your Honor.

THE COURT: Okay.

MR. GORDON: And we had told -- counsel for the FTC had called and we had confirmed that we would not be objecting, and the same is true with the Generic Pharma brief that was filed, your Honor.

THE COURT: So what's left in the Generic -- in the other brief that was filed?

MR. GORDON: The underlying brief, the dispositive motion? We have -- we have a reply due on March 22nd, your Honor.

THE COURT: And would that be the end of the briefing?

MR. GORDON: I imagine so, your Honor. No, we had just -- we have just received ourselves last night the amicus briefs, so I say that having only looked -- we had the chance to look at them quickly, but I do believe today that the March 22nd brief will be the last brief filed.

THE COURT: Well, what about the defendants' argument that the phase discovery really alleviates any alleged prejudice to the plaintiff if the requests are -- if you play it out, you'll have 30 days to respond to any

requests anyway. Maybe the motion will have -- you know, the briefing will be completed on the motion by then and I'm sure there will be objections to the scope of the request. So by the time you end up actually responding to this, quote, "limited core document request," any prejudice is very minor, if at all.

MR. GORDON: The problem, your Honor, of even going through the process of written -- the process of receiving, analyzing, objecting to discovery requests and having to -- I mean, if we're going to be put in that position, we're going to have -- I think we're going to be in the position of having to serve discovery going back the other way, it is not without substantial costs on its own. When we receive the requests, I mean, part of the thing we have to engage in as a recipient of a document request in deciding how to respond and what we're going to object to and what we're not going to object to is going through a process of -- of beginning the process of searching for the documents that are called for, figuring out what's available, where it is, where would the burden lie. It's not as simple as reading a document and coming up with a legal position as to whether or not the request is objectionable, it does require scratching beneath the surface and doing investigation into the client's files and documents in light of the requests.

The other thing I wanted to respond to and I think

it relates to your question, your Honor, is Counsel's suggestion that the Court's decision -- if I understood their argument, that the Court's decision on the dispositive motion wouldn't affect the type of documents being sought in the initial phase. So if we were to lose the initial motion -- dispositive motion rather, then we would still have to produce no matter what the Court did in that decision, we would still have to produce the documents that were called for in their first phase. First of all, obviously if the Court grants our motion, which we believe is likely, then we won't have to produce anything or engage in any of this process. Secondly, one of the things that Counsel mentioned in that litany of documents that they would be looking for are documents that underline the creation of the REMS program, and this goes to the kind of nature of the issues at issue in the underlying dispositive motion. This case is not about the scope or the elements of Actelion's REMS program.

The defendants have in their opposition to the motion tried to suggest that this case goes beyond just a refusal to deal and includes a broad scheme, including the creation of the REMS program and the elements of safe use that are contained in the REMS program. The problem with that, your Honor, is if you look at their underlying pleadings, there are no facts alleged which if true would establish that the elements of safe use in Actelion's REMS

product -- REMS program are not reasonably necessary for patient safe -- patient safety or that Actelion has used somehow the REMS program for purposes that are not connected with patient safety. The REMS program is a red herring. What this is about, what this case is about -- so documents about the creation of the REMS program, the basis for the elements of safe use in the REMS program, there are no allegations that any of those -- the elements of safe use are not necessary for patient safety. So that's all a red herring.

What this case is really about, and this is why we brought the case, it's about a simple legal issue, which is does Actelion have the obligation to sell product and do all the ancillary things that go along with selling products in terms of monitoring the safe use of that product, do they have an actual legal obligation to do so against their will? It's a simple legal question. And the fact that we filed a lawsuit -- you know, Counsel seemed to suggest that since we filed a lawsuit we should have to engage in discovery --

THE COURT: Well, I think the argument is, if you file a lawsuit, you know you're going to have discovery. It's disingenuous, I think was the term, to file a lawsuit and then argue that you're being prejudiced because you have to engage in discovery.

MR. GORDON: No, because we filed the lawsuit to

enforce our legal rights and to seek a declaration of our legal rights on an issue that we believe can be decided as a matter of law.

THE COURT: So --

MR. GORDON: We had to come to court to get that relief, but it's a legal issue, and that's why we filed our motion for judgment on the pleadings.

THE COURT: So it's the declaratory-relief aspect of the complaint that you believe differentiates this case from other cases for stays?

MR. GORDON: Correct. In terms of to the extent that it would be relevant that Actelion initiated this lawsuit, we initiated the lawsuit for declaratory relief on what we believed to be a legal issue.

THE COURT: What about the defendants' argument that there is case law in this district that requires the Court to find the dispositive motion to be the standard articulated in Judge Hammer and Judge Schneider's opinions?

MR. GORDON: I think -- I think that the defendants read far too much into that language, because it would -- if taken to the conclusion that they take from it, it would require the Magistrate Judge in this case, you, to effectively rule on the underlying motion. And I think if you look at those cases, that language arose in cases where there were other factors and elements that were at play that

went into the court's exercise of discretion. For example in the Castro case, if I'm not mistaken, I believe discovery had already begun in that case. If you look at the Lipitor case, that case had been pending for well over a year when the stay issue had come up. If you look at the Lehigh Bottling case, for example, that issue was -- which may not have been from this district, I think that may have been from the Middle District of Pennsylvania, but in that case the motion to dismiss wasn't truly dispositive.

So I think -- I don't think you can look at that language separate and apart from the full context of the case in which it erupts. And I think Mann in the Third Circuit has made it clear that the District Court does have discretion in these cases to weigh the factors and enter a stay when it would be appropriate and does not have to rule on the stay to do so -- I'm sorry, rule on the dispositive motion to do so.

THE COURT: Do you agree with the underlying principle however that stays are disfavored?

MR. GORDON: No, I don't disagree that stays are disfavored and should only be entered in cases where good cause has been shown, but I believe this case is -- I think this case frankly is tailor made for exercise of discretion in that way because of the nature of the underlying dispositive motion, because of the nature of the legal right

being defended here and because of the -- what should likely have been the relatively short duration of the stay.

THE COURT: All right, thank you.

Any further replies? Oh, I'm sorry, are -- okay.

MR. GORDON: I am finished, your Honor.

THE COURT: All right, thank you.

Any further reply?

MR. GOELMAN: Just one very, very brief --

THE COURT: Sure.

MR. GOELMAN: -- reference to the Third Circuit's opinion in Mann, your Honor.

THE COURT: Sure. Let me just ask you again that you state your name.

MR. GOELMAN: I'm sorry, Aitan Goelman for Apotex.

THE COURT: Okay.

MR. GOELMAN: And I'm referring to Page 239 of Mann where the court says, "As laid out above, none of Mann's claims entitle him to relief." So even the court in Mann acknowledged that a consideration of the merits of the underlying dispositive motion was relevant and in that case they found that essentially the party asking for the stay of discovery was going to prevail in the underlying motion.

Counsel for Actavis wanted to address and perhaps correct one thing that I had said in my initial colloquy with the Court.

THE COURT: Okay. Is there any objection?

MR. GORDON: No, your Honor.

THE COURT: All right, thank you. If you can just state your name, please?

MS. REEVES: Amanda Reeves on behalf of Actavis Elizabeth. Mr. Aitan was arguing on behalf of all defendants and I am doing the same.

There was just one point, this is more a point of correction than -- more a point of clarification than correction. At one point the Court asked if resolving this motion would end the case. I wanted to clarify that there are two motions pending, there is a 12(b)(6) motion and a 12(c) motion. And what the plaintiffs have done here is very strategic and sophisticated. We were going to file a Section 2 monopolization claim and they unilaterally sought a declaratory judgment action based on one right, which is the right to refuse to deal. So they have now sought to make the entire case about whether that one right exists. By doing that, they have attempted to sort of change the dialogue and suggest that our allegation that they're engaged in exclusionary conduct is not the issue. That is misleading and it isn't correct and it is belied by our pleadings.

During his discussion with the Court, Mr. Gordon suggested that there were not allegations in the complaint that would support allegations of exclusionary conduct. On

Page 23 of defendants' opposition brief, we explain that the exclusionary course of conduct is including elements that go well beyond the refusal to deal and include appropriate cites to the pleadings that support those allegations. So therefore the suggestion that there is one legal issue in this case that resolves the entire case is incorrect. If the Court, however, were to -- and this is what I believe Mr. Goelman was referring to -- grant the motion to dismiss for failure to properly plead sufficient allegations under 12(b)(6), that would of course dismiss the case, but at that point we may seek relief to replead.

THE COURT: Okay. So there's a 12(b)(6) motion against your client on the counterclaim?

MS. REEVES: Correct.

THE COURT: And your counterclaim differs from the other defendants' counterclaims?

MS. REEVES: Exactly. They do not match up perfectly, correct.

THE COURT: And you would be seeking leave to amend your counterclaim to address any deficiencies if the District Judge noted them?

MS. REEVES: Potentially, correct.

THE COURT: And what is the cause of action specifically in your counterclaim?

MS. REEVES: So we allege that the plaintiffs in

this case are engaged in the Section 2 exclusionary conduct by, among other things, designing a REMS program that precluded generic competitors from obtaining the Tracleer and Zyveska samples, by entering into contracts with wholesalers that prevented them from selling Tracleer and Zyveska to potential competitors, by refusing to deal and by taking the position that at no point will they ever be required to provide samples, even after their patent expires.

THE COURT: And each of those -- are they four separate counts?

MS. REEVES: Those are all elements of our Section 2 claim. So the Third Circuit law, which the plaintiffs do not cite in their motion, which is interesting because it is a Section 2 case, but the Third Circuit Section 2 law is quite clear, the LePage's decision and the ZF Meritor decision, which are all in point one of our argument walk through the standard, and those cases make clear that the Court should not sort of parse through the conduct and look at one element in light of a Supreme Court case that may be relevant say that if -- if plaintiffs allege an exclusionary course of conduct and the defendants come back by saying some component of that may be permissible, that the whole case then at the pleadings stage should be dismissed, the Court at that point should look at whether under Section 2 the -- in this case the defendants have alleged an anticompetitive course of

conduct under Section 2. It's more looking at whether there is an anticompetitive scheme.

THE COURT: Okay. So following up on the clarification that you wanted to advise to the Court or state to the Court, is it your position that if the plaintiff prevails on the 12(b)(6) motion the case would not be over because you would be looking to replead?

MS. REEVES: Potentially. We would need to discuss that, but that is a possibility. What I really wanted to make clear is that if the Court were to decide the 12(c) motion, the declaratory judgment motion, which the plaintiffs have brought, that we do not take the position that that would end the case.

THE COURT: And why do you take the position it would not end the case?

MS. REEVES: Because we allege an anticompetitive scheme comprised of many elements, so --

THE COURT: So the --

MS. REEVES: -- they're described on Page 23 of our brief.

THE COURT: So the refusal to deal with just one --

MS. REEVES: It's just one component. So they've done several things to eliminate competition.

THE COURT: Okay, thank you.

MS. REEVES: Thank you.

THE COURT: Any reply?

MR. GORDON: Your Honor, if I may, because Ms. Reeves did inject a few additional issues into the argument.

THE COURT: Sure. Just state your name, please.

MR. GORDON: George Gordon on behalf of the plaintiffs.

I just want to address quickly the notion that there is a -- you know, a kind of multi-prong scheme alleged -- or argued and that refusal to deal is only one of the issues. The argument I think that I tried to articulate and explain was that, yes, it is indeed true that plaintiffs have now in their motion papers in the dispositive motion suggested that this case is about more than a refusal to deal and have alleged -- made conclusory arguments about schemes and unreasonably broad REMS programs, but when you look --

THE COURT: You said plaintiff, you mean counterclaim plaintiffs?

MR. GORDON: I'm sorry, counterclaim plaintiff.

THE COURT: Okay.

MR. GORDON: Thank you, your Honor. But when you look -- when you peel -- when you look behind the rhetoric, as Twombly requires us to do, and actually look at what's pled in the counterclaims, it's not there. So the only well pled, in the sense that there are alleged facts -- we don't believe they state a claim, but the facts are there --

relates to refusal to deal. There are no facts which if true would support the other elements of the alleged, you know, scheme. It's just, you know, frankly, from our perspective, kind of empty rhetoric and conclusory assertions, and that would be part of what we were bringing to the Court's attention in our reply brief. So that's why this case is really only about the refusal to deal despite the fact that the plaintiffs are trying to broaden it, which is not surprising because I don't -- because the law is what it is on refusal to deal.

The other thing I want to make clear is that from our perspective the arguments in the 12(c) and the 12(b)(6) would dispose of the case on all aspects and would not -- would not lead one to replead. We do not argue in any aspects of our motion about technical pleading defects, our motion goes to the character of the conduct that's alleged. So for example, one of the things that Ms. Reeves' client alleges that the others do not is that the -- they bring a claim based on the distribution arrangements between Actelion and its specialty distributors. Our motion to dismiss and our motion for judgment on the pleadings with respect to those relationships goes to the character of those relationships, it's not a failure of pleading, it's not a pleading defect. Our argument is, as a matter of law, those relationships cannot be the basis of an antitrust claim.

So I just want to clarify that we're not -- you know, our motion goes to the character of the allegations; if it's denied, the case will proceed in whole or in part; if it's granted, we believe the case will end and will not leave room for repleading.

THE COURT: All right, thank you.

Is there anything further?

MS. EUN: Yes, your Honor, Eunnice Eun for Roxane.

Just to follow up on my codefendant's counsel's point on the 12(c) motion. In addition to the Section 2 claims that Ms. Reeves described, Roxane has also brought an additional claim, a Section 1 claim, against Actelion here. And so that, among the reasons that Ms. Reeves described, would be another reason why if the 12(c) motion were granted the case would not be over from our perspective.

THE COURT: Is the motion directed to the Section 1 claim?

MS. EUN: Yes, it is.

THE COURT: All right, thank you.

MR. GORDON: Your Honor, I just want to say I misspoke, I misspoke when I said it was Ms. Reeves' client that had brought the allegations based on the distributor relationships, it was actually Roxane who had brought those claims. And so my remarks on that issue were meant to go to that Section 1 issue.

THE COURT: Anything further?

MR. GOELMAN: Not from the defendants, your Honor.

MR. GORDON: Nothing further from the plaintiffs, your Honor.

THE COURT: Well, thank you, Counsel. I appreciate you driving down here in a rainy day for this argument. I'm going to reserve decision because I want to give some thought to the arguments that were raised today. I thank you for the very careful briefs and the argument today. And I'm going to close the briefing, I don't think any further briefing is necessary. Does anybody request that?

MR. GORDON: The plaintiffs do not, your Honor.

MR. GOELMAN: The defendants don't, your Honor.

THE COURT: All right. And I hope to issue a decision shortly and I think that's all we'll do today.

Thank you.

ALL: Thank you, your Honor.

THE COURT: We are adjourned.

(Hearing adjourned at 10:49 o'clock a.m.)

* * *

CERTIFICATION

I hereby certify that the foregoing is a correct transcript from the electronic sound recording of the proceedings in the above-entitled matter.

s:/Geraldine C. Laws, CET Dated 3/16/13
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